



Docket No.: 20342/1202653-US3  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Beth A. Burnside et al.

Application No.: 10/758,417

Confirmation No.: 5644

Filed: January 16, 2004

Art Unit: 1617

For: ORAL PULSED DOSE DRUG DELIVERY  
SYSTEM

Examiner: S. Wang

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:  
(Check one of the boxes A-D)

- ☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. **Patent(s) and/or U.S. Patent Application Publication(s)** on PTO/SB08 is/are not being submitted, except those specifically discussed in this IDS or the concurrently filed Third Preliminary Amendment.
- ☐ B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

- ☐ 3. Cite No(s). \_\_\_\_\_ are not in the English language.  
In accordance with 1.98(c), Applicant states:
- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.
- ☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

- ☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- ☐ 5. Other information being provided for the examiner's consideration follows:

[A/An \_\_\_\_\_ Search Report, dated \_\_\_\_\_, which issued during the prosecution of \_\_\_\_\_ Application No. \_\_\_\_\_ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

**A. Errors in the Specification**

**1. The inadvertent omission of talc blending in Example 2**

In Applicant's experiments, the pellets described in Example 2 were blended with 2% talc after they were dried. This step was inadvertently omitted from Example 2 of the specification.

Example 2 refers to "AR98I25-4," which is a reference number used internally by the Applicant (i.e., the assignee, Shire Laboratories, Inc.). See the specification as filed at page 18, line 7. Shire Analysis Report AR98I25 identifies reference number AR98I25-4 as "Amphetamine Pellets coated w/ Eudragit L30D-55, *Talc Blended*" (emphasis added). In the actual experiment conducted by the Applicant, 2% talc was blended into the final pellets, but this talc treatment is missing from Example 2.

This was an inadvertent omission. Further, talc blending (or "talc dusting") is optional. One of ordinary skill in the art would have known that the pellets could be blended with talc as a matter of routine.

Further, the specification discloses that an overcoating such as OPADRY® or OPADRY II® can optionally be applied to the pharmaceutical composition to protect the pellets from being tacky (specification as filed at page 15, lines 10-13). Talc was well-known as an anti-tackiness agent. For example, U.S. Patent No. 5,733,575, issued March 31, 1998, discloses that talc is a "detackifier" (SB/08 Tab AH, col. 3, line 28) and includes talc in exemplified enteric coating mixtures, which are applied to tablets (SB/08 Tab AH, col. 8, lines 32-45, Examples 3-28 and 31-35). U.S. Patent No. 5,618,559, issued April 8, 1997, discloses that talc is a detackifying agent and "[f]inely particulated talc ... is a preferred detackifying agent." SB/08 Tab AI, col. 5, lines 53-58. Thus, one of ordinary skill in the art would have known that the pellets described in the specification as filed could be coated with an anti-tackiness agent (e.g., talc) based on the knowledge in the art and the teachings of the specification.

The Federal Circuit has held that “a patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan.... a patentee preferably omits from the disclosure any routine technology that is well known at the time of application.” *Chiron v. Genentech*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). Moreover, the specification is not a production blueprint for a commercial product and is meant to provide reasonable guidance to one of ordinary skill. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990) (“[T]he patent document is not intended to be a production specification.”); *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962) (“Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. United States specifications have often been criticized as too cluttered with details to give an easy understanding of what the invention really is”); *Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1580 (Fed. Cir. 1991) (“[C]ertain information missing from the ... application -- for example, embedment molding -- was no more than a routine manufacturing choice. To invalidate the patent for this omission was error.”). Accordingly, the inadvertent omission of the talc in Example 2 relates to an optional detail that was well known in the art.

## **2. The inadvertent omission of OPADRY® in Example 3**

In Applicant’s experiments, the final delayed release pellets in Example 3 were coated with 2% OPADRY®. This step was unintentionally omitted from Example 3 in the application.

This error is harmless because the specification plainly discloses that OPADRY® is an overcoating layer, which can optionally be applied to compositions of the invention (including Example 3) to keep the pellets from being tacky. *See, e.g.*, specification as filed at page 15, lines 10-13. Further, the specification discloses suggested levels for a protective coating such as OPADRY®, i.e., 1 to 6%, preferably 2-3% (w/w). Page 15, lines 13-14. An invention is enabled if the examples “together with other parts of the specification” are enabling. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

Further, it was known in the art that OPADRY® could be applied to solid pharmaceutical dosage forms to prevent tackiness. For example, U.S. Patent No. 5,411,745, issued

May 2, 1995, discloses that an “overcoat of a film-former, such as Opadry®, [sic] is optionally applied to the beads. This overcoat is provided, if at all, in order to substantially reduce agglomeration of the beads.” **SB/08 Tab AL**, col. 9, lines 61-65. “[A] patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan....” *Chiron v. Genentech*, 363 F.3d 1247, 1254 (Fed. Cir. 2004); *see also*, *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990); *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962); *Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1580 (Fed. Cir. 1991).

Accordingly, one of ordinary skill in the art, reading the specification as a whole, would have known that OPADRY® could be applied to the pellets disclosed in Example 3.

### CONCLUSION

The information provided herein is submitted for consideration by the Examiner in connection with this application, and to allow the Examiner to consider the need for requesting additional information.

It is believed that there is no fee due for this submission. However, the Commissioner is authorized to charge any deficiency or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: February 15, 2007

Respectfully submitted,

By

  
Robert Schaffer

Registration No.: 31,194

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant



PTO/SB/08a/b (07-06)

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<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/758,417-Conf. #5644	
			Filing Date	January 16, 2004	
			First Named Inventor	Beth A. Burnside	
			Art Unit	1617	
			Examiner Name	S. Wang	
Sheet	1	of	7	Attorney Docket Number	20342/1202653-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-6,913,768	07-05-2005	Couch et al.	
	AB	US-6,764,696	07-20-2004	Pather et al.	
	AC	US-6,749,867	06-15-2004	Robinson et al.	
	AD	US-6,605,300	08-12-2003	Burnside et al.	
	AE	US-6,322,819	11-27-2001	Burnside et al.	
	AF	US-5,846,568	12-08-1998	Olinger et al.	
	AG	US-5,773,031	06-30-1998	Shah et al.	
	AH	US-5,733,575	03-31-1998	Mehra, et al.	
	AI	US-5,618,559	04-08-1997	Desai, et al.	
	AJ	US-5,501,861	03-26-1996	Makino et al.	
	AK	US-5,422,121	06-06-1995	Lehmann et al.	
	AL	US-5,411,745	05-02-1995	Oshlack et al.	
	AM	US-5,202,159	04-13-1993	Chen et al.	
	AN	US-5,137,733	08-11-1992	Noda et al.	
	AO	US-4,794,001	12-27-1988	Mehta et al.	
	AP	US-3,979,349	09-07-1976	H. Fink	
	AQ	US-3,365,365	01-23-1968	J.A. Butler et al.	
	AR	US-3,066,075	11-27-1962	DEUTSCH MARSHALL E	
	AS	US-3,048,526	08-07-1962	C. L. Boswell	
	AT	US-2,738,303	03-13-1956	R. H. Blythe	
	AU	US-2,099,402	11-16-1937	J. W. Keller	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	EP 0 640 337	03-01-1995	Okada Minoru		
	BB	WO-WO99/03471	01-28-1999	Atul M Mehta		
	BC	WO-WO00/25752	05-11-2000	John G Devane		
	BD	AU-109,438	01-11-1940	I. Lipowski		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner's signature		Date Considered	
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			Examiner Name	S. Wang	
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Adderall XR Package Inset, Sept. (2004)	
	CB	Agyilrah GA and Banker SB, Polymers for Enteric Coating applications, Polymers for Controlled Drug Delivery (Peter J. Tarcha ed. 1991) 39-66	
	CC	American Chemical Society, Polymer Preprints, pp. 633-634, Vol. 34, No. 1, March 1993	
	CD	Ansel, et al., Rate Controlled Dosage Forms and Drug Delivery Systems, Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed. (1995), 213-222	
	CE	Answering Expert Report of Dr. Alexander M. Klibanov, expert for Shire Laboratories, Inc., April 25, 2005	
	CF	Answering Expert Report of Robert Langer, Sc. D. Regarding United States Patent Nos. 6,322,819 and 6,605,300, expert for Shire Laboratories Inc., dated April 25, 2005	
	CG	Barr Laboratories' Objections and Responses to Plaintiff Shire Laboratories Inc.'s Fifth Set of Interrogatories (No. 17), dated September 3, 2004	
	CH	Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-1219-PKC	
	CI	Barr Laboratories' Answer, Affirmative Defenses, and Counterclaims, dated September 25, 2003	
	CJ	Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Second Set of Interrogatories (Nos. 8-11), dated February 18, 2004	
	CK	Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Fourth Set of Interrogatories (Nos.15-16), dated July 9, 2004	
	CL	Barr Laboratories' Memorandum in Support of Its Motion to Amend Its Pleadings and exhibits thereto, dated September 10, 2004	
	CM	Barr Laboratories' Memorandum in Support of Its Motion to Compel Production, dated September 13, 2004	
	CN	Barr Laboratories' Supplemental Objections and Responses to Plaintiff Shire Laboratories Inc.'s Third Set of Interrogatories (Nos. 12-14)(Redacted), dated August 27, 2004	
	CO	Barr Laboratories, Inc.'s '300 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)	
	CP	Barr Laboratories, Inc.'s '819 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)	
	CQ	Bauer, et al., Cellulose Acetate Phthalate (CAP) and Trimellitate (CAT), Coated Pharmaceutical Dosage Forms (1998), 102-104	
	CR	Bodmeier et al., the Influence of Buffer Species and Strength on Diltiazem HCl Release from Beads Coated with the Aqueous Catinoc Polymer Dispersions, <i>Eudragit RS, RL 30D</i> , <i>Pharmaceutical Research</i> Vol. 13, No. 1, 1996, 52-56	
	CS	Brown et al., Behavior and Motor Activity Response in Hyperactive Children and Plasma Amphetamine Levels Following a Sustained Release Preparation, <i>Journal of the American Academy of Child Psychiatry</i> , 19:225-239, 1980	
	CT	Brown et al., Plasma Levels of d-Amphetamine in Hyperactive Children, <i>Psychopharmacology</i> 62, 133-140, 1979	
	CU	Burns et al., A study of Enteric-coated Liquid-filled Hard Gelatin Capsules with Biphasic Release Characteristics, <i>International Journal of Pharmaceutics</i> 110 (1994) 291-296	
	CV	C. Lin et al., Bioavailability of d-pseudoephedrine and Azatadine from a Repeat Action Tablet Formulation, <i>J Int Med Res</i> (1982), 122-125	
	CW	C. Lin et al., Comparative Bioavailability of d-Pseudoephedrine from a Conventional d-Pseudoephedrine Sulfate Tablet and from a Repeat Action Tablet, <i>J Int Med Res</i> (1982) 10,	
Examiner's signature		Date Considered	

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				Examiner Name	S. Wang
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	126-128	
CX	Chan, Materials Used for Effective Sustained-Release Products, Proceedings of the International Symposium held on 29th to 31st of January 1987 (The Bombay College of Pharmacy 1988), 69-84	
CY	Chan, New Polymers for Controlled Products, Controlled Release Dosage Forms Proceedings of the International Symposium held on 29th to 31st of January 1987 (The Bombay College of Pharmacy 1988) 59-67	
CZ	Chang et al., Preparation and Evaluation of Shellac Pseudolatex as an Aqueous Enteric Coating Systems for Pellets, International Journal of Pharmaceuticals, 60 (1990) 171-173	
CA1	Charles S. L. Chiao and Joseph R. Robinson, Sustained-Release Drug Delivery Systems, Remington: The Science and Practice of Pharmacy, Tenth Edition (1995) 1660-1675	
CB1	Civil Docket For Case #: 1:03-cv-01164-GMS <i>Shire Laboratories, Inc. v. Impax Laboratories, Inc.</i> , Civil Action No. 03-CV-01164-GMS	
CC1	Civil Docket For Case #: 1:03-cv-01219-PKC-DFE <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-1219-PKC	
CD1	Civil Docket For Case #: 1:03-cv-06632-VM-DFE <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-6632-PKC	
CE1	Civil Docket For Case #: 1:05-cv-00020-GMS <i>Shire Laboratories, Inc. v. Impax Laboratories, Inc.</i> , Civil Action No. 05-20-GMS	
CF1	Cody et al., Amphetamine Enantiomer Excretion Profile Following Administration of Adderall, Journal of Analytical Toxicology, Vol. 2, October 2003, 485-492	
CG1	Complaint for Declaratory Judgment, <i>Impax Laboratories, Inc. v. Shire International Laboratories, Inc.</i> (Civ. Action No. 05772) and Exhibits attached thereto	
CH1	Daynes, Treatment of Nocturnal Enuresis with Enteric-Coated Amphetamine, The Practitioner, No. 1037, Vol. 173, November 1954	
CI1	Deposition of Transcript of Beth Burnside, dated 2/2/05	
CJ1	Deposition of Transcript of Beth Burnside, dated 2/3/05	
CK1	Deposition of Transcript of Charlotte M. McGuiness, dated 8/6/04	
CL1	Deposition of Transcript of Donald John Treacy, Jr., dated 8/31/04	
CM1	Deposition of Transcript of Edward Rudnic, dated 7/28/04	
CN1	Deposition of Transcript of James J. Harrington, dated July 27, 2005	
CO1	Deposition of Transcript of Kimberly Fiske, dated 9/17/04	
CP1	Deposition of Transcript of Richard Rong-Kun Chang, dated 1/20/05	
CQ1	Deposition of Transcript of Richard A. Couch, dated 9/14/04	
CR1	Deposition of Transcript of Robert Schaffer, dated August 17, 2005	
CS1	Deposition of Transcript of Xiaodi Guo, dated 1/24/05	
CT1	Deposition of Transcript of Xiaodi Guo, dated 7/26/04	
CU1	Deposition transcript of Honorable Gerald J. Mossinghoff and exhibits thereto, dated June 8, 2005	
CV1	Deposition Transcript of Richard Chang, dated 9/8/04	
CW1	Edward Stempel, Prolonged Drug Action, HUSA's Pharmaceutical Dispensing, Sixth Edition, 1996, 464, 481-485	
CX1	Expert Report of Dr. Joseph R. Robinson, expert for Barr Laboratories and exhibits thereto, February 28, 2005	
CY1	Expert Report of the Honorable Gerald J. Mossinghoff, expert for Barr Laboratories, Inc. and exhibits thereto, March 16, 2005	
CZ1	Freedom of Information Request Results for - Dexadrine (SmithKline Beecham): 5/20/1976 Disclosable Approval Information	
CA2	Fukumori, Coating of Multiparticulates Using Polymeric Dispersions, Multiparticulate Oral Drug Delivery (Swarbrick and Selassie eds. 1994), 79-110	
CB2	Garnett et al., Pharmacokinetic Evaluation of Twice-Daily Extended-Release	
Examiner's signature		Date Considered

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	Carbamazepine(CBZ) and Four-Times- Daily Immediate-Release CBZ in Patients with Epilepsy, <i>Epilepsia</i> 39(3): 274-279, 1998	
CC2	Glatt, The World of the Fluid Bed, Fluid Bed Systems, 1-19	
CD2	Goodhart et al., An evaluation of Aqueous Film-forming Dispersions for Controlled Release, <i>Pharmaceutical Technology</i> , April 1984, 64-71	
CE2	Greenhill et al., A Pharmacokinetic/Pharmacodynamic Study Comparing a Single Morning Dose of Adderall to Twice-Daily Dosing in Children with ADHD. <i>J. Am. Acad. Adolesc. Psychiatry</i> , 42:10, October 2003	
CF2	Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (1997)	
CG2	Guidance for Industry: Food- Effect Bioavailability and Fed Bioequivalence Studies (2002)	
CH2	Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms (1997)	
CI2	Hall HS and Pondell RE, Controlled Release Technologies: Methods, Theory, and Applications, pp. 133-154 (Agis F. Kydonieus ed. 1980)	
CJ2	Handbook of Pharmaceutical Excipients: Ethycellulose, Polymethacrylates, 4th ed. (2003), 237-240, 462-468	
CK2	Handbook of Pharmaceutical Excipients: Polymethacrylates, 2nd Ed. (1994), 361-366	
CL2	Hans-Martin Klein & Rolf W. Gunther, Double Contrast Small Bowel Follow-Through with an Acid-Resistant Effervescent Agent, <i>Investigative Radiology</i> Vol. 28, No. 7, July 1993, 581-585	
CM2	Harris, et al., Aqueous Polymeric Coating for Modified-Release Pellets, <i>Aqueous Polymeric Coating for Pharmaceutical Dosage Forms</i> (McGinity ed., 1989), 63-79	
CN2	Hawley's Condensed Chemical Dictionary 13th Ed. 1997, 584, 981	
CO2	Holt, Bioequivalence Studies of Ketoprofen: Product formulation, Pharmacokinetics, Deconvolution, and In Vitro- In Vivo correlations, Thesis submitted to Oregon State University, August 20, 1997 (1997)	
CP2	Husson et al., Influence of Size Polydispersity on Drug Release from Coated Pellets, <i>International Journal of Pharmaceutics</i> , 86 (1992) 113-121, 1992	
CQ2	Impax Laboratories Answer And Affirmative Defenses <i>Shire Laboratories, Inc. v. Impax Laboratories, Inc.</i> , Civil Action No. 03-CV-01164-GMS	
CR2	Impax Laboratories, Inc.'s First Supplemental Responses to Shire Laboratories Inc.'s First Set of Interrogatories (Nos. 11-12) dated 3/28/05	
CS2	Impax Laboratories, Inc.'s Memorandum in Support of the Motion to Amend Its Answer dated 2/25/05 and exhibits thereto	
CT2	Impax Laboratories, Inc.'s Reply Memorandum in Support of the Motion to Amend Its Answer dated 3/18/05 and exhibits thereto	
CU2	Impax Laboratories, Inc.'s First Amended Answer and Affirmative Defenses, dated May 2, 2005	
CV2	Ishibashi et al., Design and Evaluation of a New Capsule-type Dosage Form for Colon-targeted Delivery of Drugs, <i>International Journal of Pharmaceutics</i> 168, (1998) 31-40	
CW2	J. Sjogren, Controlled Release Oral Formulation technology, <i>Rate Control in Drug Therapy</i> , (1985) 38-47	
CX2	Jarowski, The Pharmaceutical Pilot Plant, <i>Pharmaceutical Dosage Forms: Tablets</i> , Vol. 3, 2nd Ed. (1990), 303-367	
CY2	Kao et al., Lag Time Method to Delay Drug release to Various Sites in the Gastrointestinal Tract, <i>Journal of Controlled Release</i> 44(1997) 263-270	
CZ2	Kiriyama et al., The Bioavailability of Oral Dosage Forms of a New HIV-1 Protease Inhibitor, KNI-272, in Beagle Dogs, <i>Biopharmaceutics &amp; Drug Disposition</i> , Vol. 17 125-234 (1996)	
CA3	Klaus Lehmann, Coating of Multiparticulates Using Polymeric Solutions, <i>Multiparticulate Oral Drug Delivery</i> (Swarbrick and Sellassie ed., 1994) 51-78	
CB3	Krowczynski & Brozyna, Extended-Release Dosage Forms, pp. 123-131 (1987)	
CC3	Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, <i>The Theory and Practice of Industrial Pharmacy</i> , Second Edition (1976) 371-373	

Examiner's signature		Date Considered	
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/758,417-Conf. #5644	
			Filing Date	January 16, 2004	
			First Named Inventor	Beth A. Burnside	
			Art Unit	1617	
			Examiner Name	S. Wang	
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CD3	Leopold & Eikeler, Eudragit E as Coating Material for the pH-Controlled Drug Release in the Topical Treatment of Inflammatory Bowel Disease (IBD), Journal of Drug Targeting, 1998, Vol. 6, No. 2, pp. 85-94	
CE3	Lin & Cheng, In-vitro Dissolution Behaviour of Spansule-type Micropellets Prepared by Pan Coating Method, Pharm. Ind. 51 No. 5 (1989) 528-531	
CF3	Liu et al., Comparative Release of Phenylpreanolamine HCl from Long-Acting Appetite Suppressant Product: Acutrim vs. Dexatrim, Drug Development and Industrial Pharmacy, 10(10), 1639-1661 (1984)	
CG3	Marcotte, et al., Kinetics of Protein Diffusion from a Poly(D, L-Lactide) Reservoir System. Journal of Pharmaceutical Sciences Vol. 79, No.5, May 1990	
CH3	Mathir, et al., In vitro characterization of a controlled-release chlorpheniramine maleate delivery system prepared by the air-suspension technique, J. microencapsulation, Vol. 14, No. 6, 743-751 (1997)	
CI3	McGough, et al., Pharmacokinetics of SL1381 (Adderall XR), an Extended-Release Formulation of Adderall, Journal of the American Academy of Child & Adolescent Psychiatry, Vol. 42, No. 6, June 2003, 684-691	
CJ3	McGraw-Hill Dictionary of Scientific and Technical Terms, 5th Ed. (1994), 97,972	
CK3	Mehta, et al., Evaluation of Fluid-bed Processes for Enteric Coating Systems, Pharmaceutical Technology, April 1986, 46-56	
CL3	Moller, Dissolution Testing of delayed Release Preparations, Proceedings of the International Symposium held on 29th to 31st of January 1987 (the Bombay College of Pharmacy 1988), 85-111	
CM3	Response to Office Action filed May 2, 2006 in U.S. Patent Application No. 11/091/010	
CN3	Office Action in U.S. Patent Application Serial No. 11/091,010, mailed February 3, 2006	
CO3	Office Action in U.S. Patent Application Serial No. 11/091,010, mailed July 13, 2006	
CP3	Response to Office Action filed July 18, 2006 in U.S. Patent Application No. 11/091,010	
CQ3	Office Action in U.S. Patent Application Serial No. 11/091,010, mailed October 10, 2006	
CR3	Office Action mailed March 2, 2005 in European Patent Application No. 99 970594.0-2123	
CS3	Opening Expert Report of Dr. Michael Mayersohn, expert for Impax Laboratories Inc. and exhibits thereto, March 12, 2005	
CT3	Opening Expert Report of Dr. Walter Chambliss, expert for Impax Laboratories, Inc. and exhibits thereto, March 15, 2005	
CU3	Order Construing The Terms Of U.S. Patent Nos. 6,322,819 And 6,605,300 <i>Shire Laboratories, Inc. v. Impax Laboratories, Inc.</i> , Civil Action No. 03-CV-01164-GMS	
CV3	PDR Drug information for Ritalin LA Capsules, April (2004)	
CW3	Pelham, et al., A Comparison of Morning-Only and Morning/Late Afternoon Adderall to Morning-Only, Twice-daily, and Three Times-Daily Methylphenidate in Children with Attention-Deficit/Hyperactivity Disorder, Pediatrics, Vol. 104, No. 6, December 1999	
CX3	Physicians' Desk Reference: Adderall, 51st Ed. (1997)	
CY3	Physicians' Desk Reference: Adderall, 56th Ed. (2002)	
CZ3	Physicians' Desk Reference: Dexedrine, 56th ed. (2002)	
CA4	Physicians' Desk Reference: Ritalin, 56th Ed. (2002)	
CB4	Porter and Bruno, Coating of Pharmaceutical Solid-Dosage Forms, 77-160	
CC4	Prescribing Information: Dexedrine, brand of dextroamphetamine sulfate (2001)	
CD4	R. Bianchini & C. Vecchio, Oral Controlled Release Optimization of Pellets Prepared by Extrusion- Spheronization Processing, IL Farmaco 44(6), 645-654, 1989	
CE4	Rambali, et al., Using experimental design to optimize the process parameters in fluidized bed granulation on a semi-full scale, International Journal of Pharmaceutics 220 (2001) 149-160	
CF4	Remington: The Science and Practice of Pharmacy, Basic Pharmacokinetics, 16th Ed. (1980), 693	
CG4	Remington: The Science and Practice of Pharmacy, Elutriation, 20th Ed.(2000), 690	

Examiner's signature		Date Considered	
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			First Named Inventor	Beth A. Burnside	
			Art Unit	1617	
			Examiner Name	S. Wang	
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CH4	Remington's Pharmaceutical Sciences, Fifteenth Edition (1975) 1624-1625	
CI4	Remington's Pharmaceutical Sciences, RPS XIV, 1700-1714	
CJ4	Reply to Barr Laboratories Inc.'s Amended Answer, Affirmative Defenses And Counterclaims <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-1219-PKC	
CK4	Reply to Barr Laboratories Inc.'s Amended Answer, Affirmative Defenses And Counterclaims <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-6632-PKC	
CL4	Rong-Kun Chang and Joseph R. Robinson, Sustained Drug Release from Tablets and Particles Through Coating, <i>Pharmaceutical Dosage Forms: Tablets</i> (Marcel Dekker, Inc. 1990), 199-302	
CM4	Rong-Kun Chang et al., Formulation Approaches for Oral Pulsatile Drug Delivery, <i>American Pharmaceutical Review</i>	
CN4	Rong-Kun Chang, A Comparison of Rheological and Enteric Properties among Organic Solutions, Ammonium Salt Aqueous Solutions, and Latex Systems of Some Enteric Polymers, <i>Pharmaceutical Technology</i> , October 1990, Vol. 14, No. 10, 62-70	
CO4	Rosen, et al., Absorption and Excretion of Radioactively Tagged Dextroamphetamine Sulfate from a Sustained-Release Preparation, <i>Journal of the American Medical Association</i> , December 13, 1965, Vol. 194, No. 11, 1203-1205	
CP4	Scheiffele, et al., Studies Comparing Kollicoat MAE 30 D with Commercial Cellulose Derivatives for Enteric Coating on Caffeine Cores, <i>Drug Development and Industrial Pharmacy</i> , 24(9), 807-818 (1998), 807-818	
CQ4	Serajuddin, et al., Selection of Solid Dosage Form Composition through Drug-Excipient Compatibility Testing, <i>Journal of Pharmaceutical Sciences</i> Vol. 88, No. 7, July 1999, 696-704	
CR4	Shargel; <i>Pharmacokinetics of Oral Absorption, Applied Biopharmaceutics &amp; Pharmacokinetics</i> . 5th Ed. (225), 164-166	
CS4	Sheen et al., Aqueous Film Coating Studies of Sustained Release Nicotinic Acid Pellets: An In-Vitro Evaluation, <i>Drug Development and Industrial Pharmacy</i> , 18(8), 851-860 (1992)	
CT4	Shire Laboratories Inc.'s Opposition to Barr Laboratories' Motion to Amend Its Answers and Counterclaims, September 15, 2004	
CU4	Slattum, et al., Comparison of Methods for the Assessment of Central Nervous System Stimulant Response after Dextroamphetamine Administration to Healthy Male Volunteers, <i>J. clin Pharmacol</i> (1996) 36,1039-1050	
CV4	Sprol's American Pharmacy: An Introduction to Pharmaceutical Techniques and Dosage Forms, 7th Ed. (1974), 387-388	
CW4	Sriamornsak, et al., Development of Sustained Release Theophylline Pellets Coated with Calcium Pectinate, <i>Journal of Controlled Release</i> 47 (1997) 221-232	
CX4	Stevens, et al., Controlled, Multidose, Pharmacokinetic Evaluation of Two Extended-Release Carbamazepine Formulations (carbatrol and Tegretol-XR), <i>Journal of Pharmaceutical Sciences</i> Vol. 87, No. 12, December 1998, 1531-1534	
CY4	Teva Notice letter dated February 21, 2005	
CZ4	Teva Notice letter dated June 1, 2005	
CA5	The Merck Index: Amphetamine, 12th Ed., 620	
CB5	The Merck Index: Amphetamine, 13th Ed. (2001), 97, 1089	
CC5	The United States Pharmacopeia 23, National Formulary 18 (1995) pp. 1791-1799	
CD5	The United States Pharmacopeia 26, National Formulary 21 (2003) pp. 2157-2165	
CE5	The United States Pharmacopeia 27, National Formulary 22 (2004) pp. 2302-2312	
CF5	Treatise on Controlled Drug Delivery, pp. 185-199 (Agis Kydonieus ed. 1992)	
CG5	Tulloch, et al., SL 1381 (Adderall XR), a Two-component, Extended-Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test formulations and Comparison of Fasted, Fed, and Sprinkled Administration, <i>PHARMACOTHERAPY</i> Vol. 22, No. 11, (2002), 1405-1415	
CH5	Vasilevska, et al., Preparation and Dissolution Characteristics of Controlled Release Diltiazem	

Examiner's signature		Date Considered	
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			Examiner Name	S. Wang	
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		Pellets, Drug Development and Industrial Pharmacy, 18(15), 1649-1661 (1992)	
	CI5	Watano, et al., Evaluation of aqueous Enteric Coated Granules Prepared by Moisture Control Method in Tumbling Fluidized Bed Process, Chem. Pharm. Bull. 42(3) 663-667 (1994)	
	CJ5	Wesdyk, et al., Factors affecting differences in film thickness of beads coated in fluidized bed units, International Journal of Pharmaceutics, 93, 101-109, (1993)	
	CK5	Wouessidjewe, Aqueous polymethacrylate Dispersions as Coating Materials for Sustained and Enteric Release Systems, S.T.P. Pharma Sciences 7(6) 469-475 (1997)	
	CL5	Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-6632-PKC, dated September 27, 2004	
	CM5	Court Docket for <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated January 8, 2007	
	CN5	Complaint in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , and exhibits thereto, Case No. 2:06 -cv-00952-SD dated March 2, 2006	
	CO5	Answer and Counterclaims in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated July 24, 2006	
	CP5	Reply To Counterclaims in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated August 16, 2006	
	CQ5	Defendants' Responses to Plaintiff Shire's First Set of Interrogatories (1-12) in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated September 20, 2006	
	CR5	Defendants' Responses to Plaintiff's First Set of Request for the Production of Documents and Things (1-70) in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated October 4, 2006	
	CS5	Plaintiff's Response to Defendants' First Set of Interrogatories in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated October 11, 2006	
	CT5	Plaintiff's Response to Defendants' First Set of Production Requests in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated October 11, 2006	
	CU5	Defendants' Responses to Plaintiff's Second Set of Requests for the Production of Documents and Things (71-80) in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated November 8, 2006	
	CV5	Defendants' Responses to Plaintiff Shire's Second Set of Interrogatories (No. 13) in <i>Shire Laboratories v. Teva Pharmaceuticals Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated November 8, 2006	
	CW5	Petition Under Section 8 and exhibits thereto, submitted to the Canadian Patent Office on December 4, 2006	
	CX5	Office Action in U.S. Patent Application Serial No. 11/091,011, mailed December 1, 2006	
	CY5	Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,011	
	CZ5	Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,010	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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